K122574

OCT 12 2012



# Section 5- 510(k) Summary of Safety and Effectiveness

**Prepared in accordance with the requirements of 21 CFR Part 807.92**

**1. Submitter:** Edan Instruments, Inc.

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Telephone: 0086-755-6856469

Fax: 0086-755-26882223

**Contact Person:** Randy Jiang

**Prepare date:** Feb 21, 2012

**2. Device name and classification:**

**Device name:** Digital Ultrasonic Diagnostic Imaging System

Models D3 and D6

**Classification:** 892.1560 System, Imaging, Pulsed echo, Ultrasonic

**Product code:** IYO

892.1570 Transducer, Ultrasonic, Diagnostic

**Product code:** ITX

**Regulatory Class:** Class II

**3. Predicate Device:** Digital Ultrasonic Diagnostic Imaging System. K091680
Manufacturer: Edan Instruments, Inc.

**4. Device Description:** D3 and D6 Digital Ultrasound Diagnostic Imaging System is a portable digital ultrasonic diagnostic system applied in ultrasound diagnostic examination of abdominal, obstetrical, small parts, gynecological, orthopedic, cardiac, and urological applications.

It is designed to produce ultrasound waves into body tissue and to present the returned echo information on the monitor, the resulting information is displayed in five display modes: B-Mode, 2B-Mode, 4B-Mode, M-Mode, B+M Mode. This system controlled by software is a Track 1 device that employs an array of probes that include linear array, convex linear array, microconvex linear array, transrectal and transvaginal with a frequency range of approximately 2.0MHz-10.0MHz.

The system consists of a main unit, transducers and other accessories.

**5. Intended Use:**

The D3 and D6 Digital Ultrasonic Diagnostic Imaging System are applicable for adult or children ultrasound evaluation in hospitals, clinics, gynecology rooms, obstetrics rooms, examination rooms, intensive care units, and emergency rooms The D3 and D6 are intended for use by or on the order of a physician or similarly qualified health care professional for ultrasound evaluation of Fetus; Abdomen; Pediatrics; Small Organ; Neonatal head; Cardiology; Peripheral Vessel; Musculo-skeleton (both Conventional and Superficial); Urology (including prostate); Transrecta and Transvagina.

**6. Effectiveness and Safety Considerations:**

**Clinical test:**
Clinical testing is not required.

**Non-clinical test:**
The following safety standards are conducted on the subject device:

1. IEC 60601-1 Electrical Safety
2. IEC 60601-1-2 Electromagnetic Compatibility
3. Acoustic output testing as per the guideline "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" dated September 9, 2008.
4. UD-2, IEC 60601-2-37
5. ISO 10993-1, ISO 10993-5 and ISO 10993-10

**7.Comparison to the predicate device**

Comparison to the predicate device, the subject device has the similar technology characteristics and has the same intended use, same design principle, same electrical classification and same accuracy. The different between the subject device and predicate device primarily includes physical specifications, display type and display mode, all the above differences do not affect the usage, safety and effectiveness, and no new question is raised regarding the safety and effectiveness.

**8. Substantially Equivalent Determination**

Verification and validation testing was conducted on the subject device. This premarket notification submission demonstrates that D3 and D6 Digital Ultrasonic Diagnostic Imaging System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

OCT 12 2012

Edan Instruments, Inc.
% Mr. Ned Devine
Senior Staff Engineer/FDA Office Coordinator
Underwriters Laboratories, Inc.
333 Pfingsten Road
NORTHBROOK IL 60062

Re: K122574
Trade/Device Name: Digital Ultrasonic Diagnostic Imaging System, Models D3 and D6
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO and ITX
Dated: September 21, 2012
Received: September 26, 2012

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Digital Ultrasonic Diagnostic Imaging System, Models D3 and D6, as described in your premarket notification:

Transducer Model Number

| D3 | D6 |
|---|---|
| C361-1/C341 | C363-1 |
| C321-1 | C362 |
| L741 | C343-1 |
| E741 | C321 |
| E611-1 | L743 |
| | E743 |
| | E613 |

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Shahram Vaezy at (301) 796-6242.

Sincerely Yours,

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure(s)

# Section 6- Indications for Use

510(k) Number (if known):

Device Name: Digital Ultrasonic Diagnostic Imaging System Models D3 and D6

The D3 and D6 Digital Ultrasonic Diagnostic Imaging System are applicable for adult or children ultrasound evaluation in hospitals, clinics, gynecology rooms, obstetrics rooms, examination rooms, intensive care units, and emergency rooms The D3 and D6 are intended for use by or on the order of a physician or similarly qualified health care professional for ultrasound evaluation of Fetus; Abdomen; Pediatrics; Small Organ; Neonatal head; Cardiology; Peripheral Vessel; Musculo-skeleton (both Conventional and Superficial); Urology (including prostate); Transrecta and Transvagina.

Prescription Use ___X___ Or Over the Counter Use _____.

(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K122574

# Diagnostic Ultrasound Indications for Use Form

## D3 Digital Ultrasonic Diagnostic Imaging System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | |
|---|---|---|---|---|---|---|---|
| | B | M | PWD | CWD | Color Doppler | Combined (Specify) | Other* (Specify) |
| Ophthalmic | | | | | | | |
| Fetal / Obstetrics | N | N | | | | N | Note 1,Noter2 |
| Abdominal | N | N | | | | N | Note 1,Noter2 |
| Intra-operative (Specify) | | | | | | | |
| Intra-operative (Neurological) | | | | | | | |
| Laparoscopic | | | | | | | |
| Pediatric | N | N | | | | N | Note 1,Noter2 |
| Small Organ (Specify) | N | N | | | | N | Note 1,Noter2 |
| Neonatal Cephalic | N | N | | | | N | Note 1,Noter2 |
| Adult Cephalic | | | | | | | |
| Transrectal | N | N | | | | N | Note 1,Noter2 |
| Transvaginal | N | N | | | | N | Note 1,Noter2 |
| Transurethral | | | | | | | |
| Musculo-skeletal **(Conventional)** | N | N | | | | N | Note 1,Noter2 |
| Musculo-skeletal **(Superficial)** | N | N | | | | N | Note 1,Noter2 |
| Intravascular | | | | | | | |
| Other (Gynecology) | N | N | | | | N | |
| Cardiac | N | N | | | | N | Note 1,Noter2 |
| Intravascular | | | | | | | |
| Peripheral vascular | N | N | | | | N | Note 1,Noter2 |
| Other (Urology) | N | N | | | | N | Note 1,Noter2 |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: This feature does not use contrast agent.

Note 2: Needle guide bracket kit

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K122574

# Diagnostic Ultrasound Indications for Use Form

## D3 with C361-1 / C341 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | |
|---|---|---|---|---|---|---|---|
| | B | M | PWD | CWD | Color Doppler | Combined (Specify) | Other* (Specify) |
| Ophthalmic | | | | | | | |
| Fetal / Obstetrics | P | P | | | | P | Note 1,Noter2 |
| Abdominal | P | P | | | | P | Note 1,Noter2 |
| Intra-operative (Specify) | | | | | | | |
| Intra-operative (Neurological) | | | | | | | |
| Laparoscopic | | | | | | | |
| Pediatric | P | P | | | | P | |
| Small Organ (Specify) | | | | | | | |
| Neonatal Cephalic | | | | | | | |
| Adult Cephalic | | | | | | | |
| Transrectal | | | | | | | |
| Transvaginal | | | | | | | |
| Transurethral | | | | | | | |
| Musculo-skeletal (**Conventional**) | | | | | | | |
| Musculo-skeletal (**Superficial**) | | | | | | | |
| Intravascular | | | | | | | |
| Other (Gynecology) | P | P | | | | P | Note 1,Noter2 |
| Cardiac | | | | | | | |
| Intravascular | | | | | | | |
| Peripheral vascular | | | | | | | |
| Other (Urology) | P | P | | | | P | Note 1,Noter2 |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: This feature does not use contrast agent.

Note 2: Needle guide bracket kit

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K122574

# Diagnostic Ultrasound Indications for Use Form

## D3 with C321-1 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | |
|---|---|---|---|---|---|---|---|
| | B | M | PWD | CWD | Color Doppler | Combined (Specify) | Other* (Specify) |
| Ophthalmic | | | | | | | |
| Fetal / Obstetrics | P | P | | | | P | Note 1,Noter2 |
| Abdominal | P | P | | | | P | Note 1,Noter2 |
| Intra-operative (Specify) | | | | | | | |
| Intra-operative (Neurological) | | | | | | | |
| Laparoscopic | | | | | | | |
| Pediatric | P | P | | | | P | Note 1,Noter2 |
| Small Organ (Specify) | | | | | | | |
| Neonatal Cephalic | | | | | | | |
| Adult Cephalic | | | | | | | |
| Transrectal | | | | | | | |
| Transvaginal | | | | | | | |
| Transurethral | | | | | | | |
| Musculo-skeletal (**Conventional**) | | | | | | | |
| Musculo-skeletal (**Superficial**) | | | | | | | |
| Intravascular | | | | | | | |
| Other (Gynecology) | P | P | | | | P | Note 1,Noter2 |
| Cardiac | P | P | | | | P | Note 1,Noter2 |
| Intravascular | | | | | | | |
| Peripheral vascular | | | | | | | |
| Other (Urology) | P | P | | | | P | Note 1,Noter2 |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: This feature does not use contrast agent.

Note 2: Needle guide bracket kit

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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Office of In Vitro Diagnostic Device Evaluation and Safety

510K K122574

# Diagnostic Ultrasound Indications for Use Form

## D3 with L741 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | |
|---|---|---|---|---|---|---|---|
| | B | M | PWD | CWD | Color Doppler | Combined (Specify) | Other* (Specify) |
| Ophthalmic | | | | | | | |
| Fetal / Obstetrics | | | | | | | |
| Abdominal | | | | | | | |
| Intra-operative (Specify) | | | | | | | |
| Intra-operative (Neurological) | | | | | | | |
| Laparoscopic | | | | | | | |
| Pediatric | | | | | | | |
| Small Organ (Specify) | P | P | | | | P | Note 1,Noter2 |
| Neonatal Cephalic | P | P | | | | P | Note 1,Noter2 |
| Adult Cephalic | | | | | | | |
| Transrectal | | | | | | | |
| Transvaginal | | | | | | | |
| Transurethral | | | | | | | |
| Musculo-skeletal (**Conventional**) | P | P | | | | P | Note 1,Noter2 |
| Musculo-skeletal (**Superficial**) | P | P | | | | P | Note 1,Noter2 |
| Intravascular | | | | | | | |
| Other (Gynecology) | | | | | | | |
| Cardiac | | | | | | | |
| Intravascular | | | | | | | |
| Peripheral vascular | P | P | | | | P | Note 1,Noter2 |
| Other (Urology) | P | P | | | | P | Note 1,Noter2 |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: This feature does not use contrast agent.

Note 2: Needle guide bracket kit

Small organ includes galactophore, thyroid gland, prostate

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Prescription Use (Per 21 CFR 801.109)

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510K K122574

# Diagnostic Ultrasound Indications for Use Form

## D3 with E741 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | |
|---|---|---|---|---|---|---|---|
| | B | M | PWD | CWD | Color Doppler | Combined (Specify) | Other* (Specify) |
| Ophthalmic | | | | | | | |
| Fetal / Obstetrics | | | | | | | |
| Abdominal | | | | | | | |
| Intra-operative (Specify) | | | | | | | |
| Intra-operative (Neurological) | | | | | | | |
| Laparoscopic | | | | | | | |
| Pediatric | | | | | | | |
| Small Organ (Specify) | | | | | | | |
| Neonatal Cephalic | | | | | | | |
| Adult Cephalic | | | | | | | |
| Transrectal | P | P | | | | P | Note 1,Noter2 |
| Transvaginal | | | | | | | |
| Transurethral | | | | | | | |
| Musculo-skeletal (**Conventional**) | | | | | | | |
| Musculo-skeletal (**Superficial**) | | | | | | | |
| Intravascular | | | | | | | |
| Other (Gynecology) | | | | | | | |
| Cardiac | | | | | | | |
| Intravascular | | | | | | | |
| Peripheral vascular | | | | | | | |
| Other (Urology) | P | P | | | | P | Note 1,Noter2 |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: This feature does not use contrast agent.

Note 2: Needle guide bracket kit

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K122574

Digital Ultrasonic Diagnostic Imaging System
510K Submission

# Diagnostic Ultrasound Indications for Use Form

## D3 with E611-1 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | |
|---|---|---|---|---|---|---|---|
| | B | M | PWD | CWD | Color Doppler | Combined (Specify) | Other* (Specify) |
| Ophthalmic | | | | | | | |
| Fetal / Obstetrics | P | P | | | | P | Note 1,Noter2 |
| Abdominal | | | | | | | |
| Intra-operative (Specify) | | | | | | | |
| Intra-operative (Neurological) | | | | | | | |
| Laparoscopic | | | | | | | |
| Pediatric | | | | | | | |
| Small Organ (Specify) | | | | | | | |
| Neonatal Cephalic | | | | | | | |
| Adult Cephalic | | | | | | | |
| Transrectal | | | | | | | |
| Transvaginal | P | P | | | | P | Note 1,Noter2 |
| Transurethral | | | | | | | |
| Musculo-skeletal (**Conventional**) | | | | | | | |
| Musculo-skeletal (**Superficial**) | | | | | | | |
| Intravascular | | | | | | | |
| Other (Gynecology) | P | P | | | | P | Note 1,Noter2 |
| Cardiac | | | | | | | |
| Intravascular | | | | | | | |
| Peripheral vascular | | | | | | | |
| Other (Urology) | P | P | | | | P | Note 1,Noter2 |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: This feature does not use contrast agent.

Note 2: Needle guide bracket kit.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K122574

# Diagnostic Ultrasound Indications for Use Form

## D6 Digital Ultrasonic Diagnostic Imaging System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | |
|---|---|---|---|---|---|---|---|
| | B | M | PWD | CWD | Color Doppler | Combined (Specify) | Other* (Specify) |
| Ophthalmic | | | | | | | |
| Fetal / Obstetrics | N | N | | | | N | Note 1,Noter2 |
| Abdominal | N | N | | | | N | Note 1,Noter2 |
| Intra-operative (Specify) | | | | | | | |
| Intra-operative (Neurological) | | | | | | | |
| Laparoscopic | | | | | | | |
| Pediatric | N | N | | | | N | Note 1,Noter2 |
| Small Organ (Specify) | N | N | | | | N | Note 1,Noter2 |
| Neonatal Cephalic | N | N | | | | N | Note 1,Noter2 |
| Adult Cephalic | | | | | | | |
| Transrectal | N | N | | | | N | Note 1,Noter2 |
| Transvaginal | N | N | | | | N | Note 1,Noter2 |
| Transurethral | | | | | | | |
| Musculo-skeletal **(Conventional)** | N | N | | | | N | Note 1,Noter2 |
| Musculo-skeletal **(Superficial)** | N | N | | | | N | Note 1,Noter2 |
| Intravascular | | | | | | | |
| Other (Gynecology) | | | | | | | |
| Cardiac | N | N | | | | N | Note 1,Noter2 |
| Intravascular | | | | | | | |
| Peripheral vascular | N | N | | | | N | Note 1,Noter2 |
| Other (Urology) | N | N | | | | N | Note 1,Noter2 |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: This feature does not use contrast agent.

Note 2: Needle guide bracket kit

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K122574

# Diagnostic Ultrasound Indications for Use Form

## D6 with C363-1 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | |
|---|---|---|---|---|---|---|---|
| | B | M | PWD | CWD | Color Doppler | Combined (Specify) | Other* (Specify) |
| Ophthalmic | | | | | | | |
| Fetal / Obstetrics | P | P | | | | P | Note 1,Noter2 |
| Abdominal | P | P | | | | P | Note 1,Noter2 |
| Intra-operative (Specify) | | | | | | | |
| Intra-operative (Neurological) | | | | | | | |
| Laparoscopic | | | | | | | |
| Pediatric | P | P | | | | P | Note 1,Noter2 |
| Small Organ (Specify) | | | | | | | |
| Neonatal Cephalic | | | | | | | |
| Adult Cephalic | | | | | | | |
| Transrectal | | | | | | | |
| Transvaginal | | | | | | | |
| Transurethral | | | | | | | |
| Musculo-skeletal (**Conventional**) | | | | | | | |
| Musculo-skeletal (**Superficial**) | | | | | | | |
| Intravascular | | | | | | | |
| Other (Gynecology) | P | P | | | | P | Note 1,Noter2 |
| Cardiac | | | | | | | |
| Intravascular | | | | | | | |
| Peripheral vascular | | | | | | | |
| Other (Urology) | P | P | | | | P | Note 1,Noter2 |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: This feature does not use contrast agent.

Note 2: Needle guide bracket kit

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K120574

# Diagnostic Ultrasound Indications for Use Form

## D6 with C362 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | |
|---|---|---|---|---|---|---|---|
| | B | M | PWD | CWD | Color Doppler | Combined (Specify) | Other* (Specify) |
| Ophthalmic | | | | | | | |
| Fetal / Obstetrics | P | P | | | | P | Note 1,Noter2 |
| Abdominal | P | P | | | | P | Note 1,Noter2 |
| Intra-operative (Specify) | | | | | | | |
| Intra-operative (Neurological) | | | | | | | |
| Laparoscopic | | | | | | | |
| Pediatric | P | P | | | | P | Note 1,Noter2 |
| Small Organ (Specify) | | | | | | | |
| Neonatal Cephalic | | | | | | | |
| Adult Cephalic | | | | | | | |
| Transrectal | | | | | | | |
| Transvaginal | | | | | | | |
| Transurethral | | | | | | | |
| Musculo-skeletal (**Conventional**) | | | | | | | |
| Musculo-skeletal (**Superficial**) | | | | | | | |
| Intravascular | | | | | | | |
| Other (Gynecology) | P | P | | | | P | Note 1,Noter2 |
| Cardiac | | | | | | | |
| Intravascular | | | | | | | |
| Peripheral vascular | | | | | | | |
| Other (Urology) | P | P | | | | P | Note 1,Noter2 |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: This feature does not use contrast agent.

Note 2: Needle guide bracket kit

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K122574

# Diagnostic Ultrasound Indications for Use Form

## D6 withC343-1 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | |
|---|---|---|---|---|---|---|---|
| | B | M | PWD | CWD | Color Doppler | Combined (Specify) | Other* (Specify) |
| Ophthalmic | | | | | | | |
| Fetal / Obstetrics | P | P | | | | P | Note 1,Noter2 |
| Abdominal | P | P | | | | P | Note 1,Noter2 |
| Intra-operative (Specify) | | | | | | | |
| Intra-operative (Neurological) | | | | | | | |
| Laparoscopic | | | | | | | |
| Pediatric | P | P | | | | P | Note 1,Noter2 |
| Small Organ (Specify) | | | | | | | |
| Neonatal Cephalic | | | | | | | |
| Adult Cephalic | | | | | | | |
| Transrectal | | | | | | | |
| Transvaginal | | | | | | | |
| Transurethral | | | | | | | |
| Musculo-skeletal (**Conventional**) | | | | | | | |
| Musculo-skeletal (**Superficial**) | | | | | | | |
| Intravascular | | | | | | | |
| Other (Gynecology) | P | P | | | | P | Note 1,Noter2 |
| Cardiac | | | | | | | |
| Intravascular | | | | | | | |
| Peripheral vascular | | | | | | | |
| Other (Urology) | P | P | | | | P | Note 1,Noter2 |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: This feature does not use contrast agent.

Note 2: Needle guide bracket kit

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# Diagnostic Ultrasound Indications for Use Form

## D6 with C321 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | |
|---|---|---|---|---|---|---|---|
| | B | M | PWD | CWD | Color Doppler | Combined (Specify) | Other* (Specify) |
| Ophthalmic | | | | | | | |
| Fetal / Obstetrics | P | P | | | | P | Note 1,Noter2 |
| Abdominal | P | P | | | | P | Note 1,Noter2 |
| Intra-operative (Specify) | | | | | | | |
| Intra-operative (Neurological) | | | | | | | |
| Laparoscopic | | | | | | | |
| Pediatric | P | P | | | | P | Note 1,Noter2 |
| Small Organ (Specify) | | | | | | | |
| Neonatal Cephalic | | | | | | | |
| Adult Cephalic | | | | | | | |
| Transrectal | | | | | | | |
| Transvaginal | | | | | | | |
| Transurethral | | | | | | | |
| Musculo-skeletal (**Conventional**) | | | | | | | |
| Musculo-skeletal (**Superficial**) | | | | | | | |
| Intravascular | | | | | | | |
| Other (Gynecology) | P | P | | | | P | Note 1,Noter2 |
| Cardiac | P | P | | | | P | Note 1,Noter2 |
| Intravascular | | | | | | | |
| Peripheral vascular | | | | | | | |
| Other (Urology) | P | P | | | | P | Note 1,Noter2 |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: This feature does not use contrast agent.

Note 2: Needle guide bracket kit

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# Diagnostic Ultrasound Indications for Use Form

## D6 with L743 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | |
|---|---|---|---|---|---|---|---|
| | B | M | PWD | CWD | Color Doppler | Combined (Specify) | Other* (Specify) |
| Ophthalmic | | | | | | | |
| Fetal / Obstetrics | | | | | | | |
| Abdominal | | | | | | | |
| Intra-operative (Specify) | | | | | | | |
| Intra-operative (Neurological) | | | | | | | |
| Laparoscopic | | | | | | | |
| Pediatric | | | | | | | |
| Small Organ (Specify) | P | P | | | | P | Note 1,Noter2 |
| Neonatal Cephalic | P | P | | | | P | Note 1,Noter2 |
| Adult Cephalic | | | | | | | |
| Transrectal | | | | | | | |
| Transvaginal | | | | | | | |
| Transurethral | | | | | | | |
| Musculo-skeletal (**Conventional**) | P | P | | | | P | Note 1,Noter2 |
| Musculo-skeletal (**Superficial**) | P | P | | | | P | Note 1,Noter2 |
| Intravascular | | | | | | | |
| Other (Gynecology) | | | | | | | |
| Cardiac | | | | | | | |
| Intravascular | | | | | | | |
| Peripheral vascular | P | P | | | | P | Note 1,Noter2 |
| Other (Urology) | P | P | | | | P | Note 1,Noter2 |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: This feature does not use contrast agent.

Note 2: Needle guide bracket kit

Small Organ includes galactophore, thyroid gland, prostate

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# Diagnostic Ultrasound Indications for Use Form

## D6 with E743 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | |
|---|---|---|---|---|---|---|---|
| | B | M | PWD | CWD | Color Doppler | Combined (Specify) | Other* (Specify) |
| Ophthalmic | | | | | | | |
| Fetal / Obstetrics | | | | | | | |
| Abdominal | | | | | | | |
| Intra-operative (Specify) | | | | | | | |
| Intra-operative (Neurological) | | | | | | | |
| Laparoscopic | | | | | | | |
| Pediatric | | | | | | | |
| Small Organ (Specify) | | | | | | | |
| Neonatal Cephalic | | | | | | | |
| Adult Cephalic | | | | | | | |
| Transrectal | P | P | | | | P | Note 1,Noter2 |
| Transvaginal | | | | | | | |
| Transurethral | | | | | | | |
| Musculo-skeletal (**Conventional**) | | | | | | | |
| Musculo-skeletal (**Superficial**) | | | | | | | |
| Intravascular | | | | | | | |
| Other (Gynecology) | | | | | | | |
| Cardiac | | | | | | | |
| Intravascular | | | | | | | |
| Peripheral vascular | | | | | | | |
| Other (Urology) | P | P | | | | P | Note 1,Noter2 |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: This feature does not use contrast agent.

Note 2: Needle guide bracket kit

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# Diagnostic Ultrasound Indications for Use Form

## D6 with E613 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | |
|---|---|---|---|---|---|---|---|
| | B | M | PWD | CWD | Color Doppler | Combined (Specify) | Other* (Specify) |
| Ophthalmic | | | | | | | |
| Fetal / Obstetrics | P | P | | | | P | Note 1,Noter2 |
| Abdominal | | | | | | | |
| Intra-operative (Specify) | | | | | | | |
| Intra-operative (Neurological) | | | | | | | |
| Laparoscopic | | | | | | | |
| Pediatric | | | | | | | |
| Small Organ (Specify) | | | | | | | |
| Neonatal Cephalic | | | | | | | |
| Adult Cephalic | | | | | | | |
| Transrectal | | | | | | | |
| Transvaginal | P | P | | | | P | Note 1,Noter2 |
| Transurethral | | | | | | | |
| Musculo-skeletal (**Conventional**) | | | | | | | |
| Musculo-skeletal (**Superficial**) | | | | | | | |
| Intravascular | | | | | | | |
| Other (Gynecology) | P | P | | | | P | Note 1,Noter2 |
| Cardiac | | | | | | | |
| Intravascular | | | | | | | |
| Peripheral vascular | | | | | | | |
| Other (Urology) | P | P | | | | P | Note 1,Noter2 |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: This feature does not use contrast agent.

Note 2: Needle guide bracket kit.

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